DC | HEALTH

District of Columbia Department of Health **Institutional Review Board for Public Health**		**PROCEDURE 200.101** Implementing Office: Center for Policy Planning and Evaluation Training Required: Yes Originally Issued: May 1, 2002 Revised/Reviewed: DEC 20 2021 **(Second Revision)**
Approved by: LaQuandra S. Nesbitt MD, MPH; Agency Director	**Review by Legal Counsel:** Phillip Husband, Esq.; General Counsel	**Effective Date:** DEC 20 2021 **Valid Through Date:** DEC 20 2024

I. Authority	Reorganization Plan No. 4 of 1996; Mayor's Order 1997-42; 45 Code of Federal Regulations §46; 21 Code of Federal Regulations 56.108; 21st Century Cures Act (Pub. L. 114-255).
II. Reason for the Policy	DC Health supports an Institutional Review Board for Public Health (IRBPH) as a resource for researchers carrying out studies to further the public health. The IRBPH plays a critical role by evaluating research projects in advance, and on a continuing basis, to ensure that they reflect the highest ethical standards, and are feasible and desirable to carry out under DC Health sponsorship. The IRBPH performs a unique function on behalf of DC Health by ensuring that that the research contributes to the overall well-being of the community and improves the quality of services provided in the District of Columbia. The IRBPH has the authority to review proposed research activities and approve or disapprove proposed research activities, including requiring additional information prior to voting on the proposal, or making approval contingent upon modifications to the proposal. The IRBPH performs a unique government function on behalf of DC Health by ensuring that that the research contributes to the overall well-being of the community and improves the quality of services provided in the District of Columbia. Through the IRBPH, DC Health provides a resource for researchers carrying out studies to further the public health and conduct ongoing reviews of approved research proposals to ensure that

	researchers are remaining in compliance with the highest ethical principles. Through the IRBPH, DC Health provides a protocol for an orderly system for submitting research proposals. Additionally, the protocol is necessary to provide safeguards against risk to human subjects in general; to those who are vulnerable and require additional safeguards, in particular, as well as to ensure that the research contributes to the overall well-being of the community and improves the quality of services provided in the District of Columbia. A protocol is needed to provide an orderly system for submitting research proposals. Additionally, a protocol is necessary to provide safeguards against risk to human subjects in general; to those who are vulnerable and require additional safeguards, in particular, as well as to ensure that the research contributes to the overall well-being of the community and improves the quality of services provided in the District of Columbia.
III. Applicability	This policy applies to all Department of Health (DC Health) employees, contract employees, volunteers, interns, summer youth employees, and federal employees assigned to the District government (collectively referred to herein as "employees" or "DC Health employees").
IV. Policy Statement	The IRBPH is a permanent committee consisting of no greater than ten (10) persons, including the Chairperson and Co-Chairperson, whose backgrounds and expertise qualify them to contribute significantly to a complete and adequate review of research activities research activities that involve District of Columbia residents, visitors or persons doing business in the District of Columbia conducted within DC Health's aegis. The IRBPH has the authority to review proposed research activities and approve or disapprove proposed research activities, including requiring additional information prior to voting on the proposal, or making approval contingent upon modifications to the proposal. Additionally, the IRBPH is responsible for conducting ongoing reviews of approved research proposals to ensure that researchers are remaining in compliance with the highest ethical principles. The IRBPH maintains the authority to require safeguards, in particular, as well as ensure that the research contributes to the overall well-being of the community and improves the quality of services provided in the District of Columbia.

Because of the vital role IRBPH provides to the District of Columbia, any multi-institutional research must rely upon the IRBPH. The IRBPH can not delegate their duties as the relying institution to other institutions or research partners.

The Chairperson will be selected by the Director of DC Health ("the Director"), while other members of the IRBPH will be designated by the Director, or designee, in consultation with the Chairperson. Alternate members may be nominated and appointed to act for regular members in their absence. At least annually, the Director, in consultation with the Chairperson, shall review all appointments to the IRBPH. New members may be designated in the interim.

A minimum of fifty percent of IRBPH members shall be District of Columbia residents. Membership of the IRBPH shall also include:

1. A commitment to a diverse representation of members of the District of Columbia community, but no selection can be made solely based on gender or race/ethnicity;
2. Members of multiple professions or disciplines, including: at least one (1) member whose primary area of expertise or area of training is in a scientific or health-related field; and at least one (1) member whose primary concerns are in a nonscientific area; for example: lawyers, ethicists, or members of the clergy;
3. At least one (1) member who is not otherwise affiliated with the Department and who is not part of the immediate family of a person who is affiliated with the Department;
4. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

No IRBPH member may participate in an initial or continuing review of any project in which s/he has a conflicting interest, except to provide information requested by the IRBPH. Any member who has been involved in the approval process of a protocol under consideration or determined to have a conflict of interest, shall not be eligible to vote.

All IRBPH members are required to complete annual training in research ethics and human subject protections. DC Health will arrange training in collaboration with federal partners. The training may occur through an e-learning module.

The IRBPH shall conduct initial and continuing reviews on all research proposals if any of the following is true:

1. The Principal Investigator is a DC Health employee;
2. The human subjects in the research proposal are DC Health employees;
3. The human subjects in the research proposal are receiving services funded by DC Health;
4. The research is funded with federal funds or grants;
5. The researchers or administrators, are requesting identified data from the DC Health Vital Records Division;
6. The researchers are receiving funding from DC Health;
7. Researchers recruiting human subjects from DC Health space;
8. The human subjects are students.

The Chairperson has the authority to refer any research proposal not meeting the above criteria to a different Institutional Review Board (IRB) operating in the District of Columbia.

The IRBPH will meet once each month on a set schedule. The schedule will be published on the Department's website. The Chairperson, or Co-Chairperson, has the discretion to cancel a meeting if no proposals were received that month. The Chairperson also has the discretion to call an ad hoc meeting for any reason. The IRBPH may not vote on a research proposal unless more than fifty percent of members are present. Alternate members may attend to meet this requirement.

The IRBPH shall evaluate the proposal in terms of the scientific merit, the risks to the subjects involved, the adequacy of protections against these risks, the potential benefit of the proposed research to the subjects and others, the importance of the knowledge to be gained, and whether the research aligns with the of respects for person, beneficence, and justice outlined in The

	Belmont Report. An IRBPH evaluation, full or expedited, will include ensuring the following elements are satisfied: 1. The design and method of the proposal are scientifically sound and the research methods are appropriate to the objectives of the research and the field of study; 2. The proposal conforms to the legal and medical requirements concerning the administration of pharmacological agents, psychological tests, or any other treatment or assessment that carries potential patient risk; 3. Selection of subjects is equitable. In making this assessment, the IRBPH should take into account the purposes of the research and the setting in which the research will be conducted; 4. Where appropriate, the research plan must include adequate provisions to protect the safety and privacy of the subjects and to maintain the confidentiality of data; 5. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes; 6. Risks to subjects are reasonable in relation to anticipated benefits, and to the importance of the knowledge that may reasonably be obtained from the results. In evaluating risks and benefits, the IRBPH should consider the full range of risks and benefits that may result from the research; 7. Where applicable, the PI has provided assurances that Food and Drug Administration (FDA) approval is being sought for the use of experimental drugs, drugs not yet approved by the FDA for general use, or established drugs which are to be administered by routes, in dosages, or for conditions not in accordance with approved FDA requirements; 8. A thorough evaluation of the researchers' plan to obtain informed consent, and the informed consent form that will be used. The IRBPH may approve an altered consent procedure which does not include, or alters, some or all elements of informed consent (see definition below) or waive the requirements to obtain informed consent provided the IRBPH finds and documents that:

	1. The research involves no more than minimal risk to the subjects; 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects; 3. The research could not practically be carried out without the waiver or alteration; and 4. Whenever appropriate, the subjects will be provided with additional information after participation. If the IRBPH concludes that there is risk to subjects, per Title 45 Code of Federal Regulations Part 46 Subpart A (45 CFR 46) "Basic HHS Policy for Protection of Human Research Subjects" it must determine if the following conditions are met: 1. Rights and welfare of subjects; 2. Risks to subjects are minimized. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, IRBPH should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRBPH should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility; 3. Selection of subjects is equitable. In making this assessment the IRBPH should take into account the purposes of the research and the setting in which the research will be conducted. The IRBPH should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons; 4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § 46.116; 5. Informed consent will be appropriately documented or appropriately waived in accordance with § 46.117;

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. IRBPH shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 46.116. IRBPH may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRBPH judgment the information would meaningfully add to the protection of the rights and welfare of subjects;

There must be Informed Consent by means of a witnessed signed Informed Consent Form, which in addition to the usual required provisions of such a form, must contain the following statement: "In the event of any physical injury resulting from participating in the protocol, DC Health will provide emergency medical treatment to the individual in need of assistance. The pursuit of further treatment, if indicated, will be the responsibility of the individual. Moreover, any resulting illness or disablement will not be considered work-related and thus the individual will not be eligible for Workers' Compensation."

The IRBPH may approve research proposals where children are involved as subjects if it finds that no greater than minimal risk to children is presented, only if the IRBPH finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

The IRBPH may approve research proposals that find that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRBPH finds that:

1. The risk is justified by the anticipated benefit to the subjects;
2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

	3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408. The IRBPH may approve research proposals that find if it finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRBPH finds that: 1. The risk represents a minor increase over minimal risk; 2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; 3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and 4. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians. The IRBPH may only approve research proposals where prisoners are involved if: 1. The research under review represents one of the categories of research permissible under §46.306(a)(2); 2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired; 3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers; 4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in

	writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project; 5. The information is presented in language which is understandable to the subject population; 6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and 7. Where the IRBPH finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. The IRBPH may approve research involving pregnant women or fetuses (conditions for approving research specifically involving neonates can be found in Title 45 DFR 46.205) if all of the following conditions are met: 1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses; 2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means; 3. Any risk is the least possible for achieving the objectives of the research; 4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is

	the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part; 5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest; 6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; 7. For children as defined in Title 45 CFR §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D; 8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; 9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and 10. Individuals engaged in the research will have no part in determining the viability of a neonate. DC Health employees may participate as a human subject in a research protocol under the following conditions: 1. They may only be compensated for participating if randomly selected out of the general population; 2. They must either voluntarily request to participate or be recruited by one of the investigators; 3. A supervisor has not, nor appeared to, influence or manipulate the selection process; 4. If the employee's participation will require any absence from his/her work station, and/or impair his/her work performance, the employee must receive approval to participate from his/her supervisor; and 5. If the employee is recruited for external research, no DC Health resources may be used by the participating employee as a part of their participation in the study.

	When cooperating institutions conduct joint research, the institutions may use joint review, reliance upon the review of another qualified IRBPH, or similar efforts aimed at avoidance of duplication of effort. However, in research activities involving patients receiving DC Health-funded services, or records of those services, the Department IRBPH (or Chairperson or Co-Chair, if expedited or exempt review is appropriate) shall review the proposal to ensure that it adequately safeguards the rights and welfare (including privacy) of subject patients. The Chairperson of the IRBPH shall determine, in consultation with IRBPH members, whether review by another IRBPH is sufficient to recommend approval of the research activity. The applicant will complete the Review Category Selection Tool to determine if s/he may apply for an exemption from the IRBPH, or an expedited review. If the Review Category Selection Tool indicates that the research proposal may be considered for exemption, the Principal Investigator must submit an Application for Exemption with a written justification appended. At a minimum, the written justification must include an explanation of how the Principal Investigator will protect the privacy of subjects and maintain the confidentiality of data. The Chairperson or Co-Chair will evaluate the Application for Exemption, and either grant an exemption, or deny the request and direct the Principal Investigator in writing to complete an Application for Research Involving Human Subjects. The Chairperson or Co-Chair may conclude that specific activities, otherwise considered exempt, require further review, and may direct the Principal Investigator to submit an Application for Research with Human Subjects. If the Review Category Selection Tool indicates that the research proposal may be considered for expedited review, the Principal Investigator must submit an Application for Research Involving Human Subjects. The Chairperson will evaluate the Application for Research Involving Human Subjects, and inform the Principal Investigator in writing whether the proposal will receive an expedited or full IRBPH review. In cases where the Principal Investigator, or any other investigator, is a DC Health employee (including a student under the

	supervision of a DC Health employee), that employee must receive approval from his/her direct supervisor, as well as the program manager responsible for any patients/participants to be involved in the research, in advance of submitting an application to the IRBPH. At a minimum, the employee must inform these managers of the research methodology; an estimate of the cost of the research, the time required of DC Health staff or other individuals, including patients. These managers will consider the following when evaluating whether the research proposal may advance to an IRBPH application: 1. Feasibility of the proposal in terms of cost, personnel, equipment, and space; 2. The likelihood that the results of the proposed research will be of significant importance to warrant the anticipated costs; 3. The potential benefits to DC Health and the community; 4. Possible disruptive effects on DC Health operations; 5. Whether the invitation of patients to participate in the research and the participation itself, will interfere with the health care of any patient. The IRBPH will ensure the Principal Investigator is aware of the responsibility to inform, and consult with appropriate clinical staff, about contemplated studies involving participation of their patients, and for monitoring research projects to ensure compliance with DC Health policies and standards. The guidance will include that, in any somatic intervention, there is a liaison, and supervision by the physician responsible for the well-being of the patient. An application for a full, or expedited, review must include the following materials: 1. A complete Application for Research Involving Human Subjects; 2. A cover letter requesting review and a brief summary of the study; 3. A brief description of the area of proposed study, including the hypothesis to be tested, where appropriate, and the information expected from the study;

4. A review of the literature, including a brief summary of research already accomplished with emphasis on any significant contributions;
5. An outline of precisely what is to be studied, tests or instruments to be administered, and what is to be done with the sample. This section should be sufficiently clear and complete to enable the IRBPH to arrive at an independent judgment of the scientific merit of the research. The investigator should include copies of little known scales or tests if their submission will facilitate review;
6. Possible risks and benefits to subject population. Particular attention should be given to the following factors in assessing risks and benefits:
   a. Interference with ongoing treatment programs;
   b. Inconvenience or psychological stress that might arise because of the nature of the subjects being studied;
   c. Measures that will be taken to prevent potential embarrassment or compromise of the subjects' rights to privacy;
   d. A precise description of the procedures which the investigator and staff will follow to provide confidentiality of the information generated by the study and of the identity of the subjects. This includes: plans to obtain consent of the subjects before furnishing information to organizations and to individuals other than the study staff; any plan to make audio or visual recordings of subjects; obtain the subject's consent for any long-term retention of the recordings; and for any showing of visual recordings or playing of audio recordings, including for educational purposes, and to persons other than those conducting the study;
   e. In the case of pharmacological research, a detailed outline of known or suspected risks must be presented. Information must be provided to document the competence of the facility and the investigators to deal with such complications as may be reasonably foreseen;
   f. Any physical or psychological risk associated with the project, a statement as to the investigator's ability, and the institutional resources available, to provide

adequate treatment to the subject should any complications occur;

g. Whether benefits to the subject are likely to be immediate or whether they are anticipated as providing new knowledge which might, in the future, lead to improved treatment programs.

7. State plan for analyzing the data, including:
   a. How the raw data will be used;
   b. The method by which findings will be evaluated;
   c. Statistical or other means of evaluation;
   d. How the data will be stored;
   e. How and when the data will be transmitted;
   f. How and when the data will be destroyed.
8. Confidentiality Agreements signed by any employee, consultant, subcontractor, agent, representative or any other persons involved in the research who will have access to confidential data/information. It should include that he/she recognizes the individual responsibility to hold such data/information in confidence, and is also aware of the potential legal penalties for unauthorized disclosure of confidential data/information;
9. Bibliography. References to literature cited should be included. Copies of pertinent articles may be attached if their submission will facilitate review;
10. Curriculum Vitae. When submitting a proposal, the principal investigator and project supervisor (when appropriate) should provide information on education and training which attests to their scientific qualifications to conduct the proposed research;
11. Informed consent. It should address the method for approaching prospective subjects and obtaining consent. The investigator must attach a proposed informed consent form, unless the investigator is recommending that the IRBPH waive the requirement for a signed consent form;
12. Letters of agreement to collaborate from researchers partnering with DC Health;
13. Where applicable, approval from the Food and Drug Administration (FDA) for the use of experimental drugs, drugs not yet approved by the FDA, or established drugs to be administered.

	An expedited IRBPH review will be evaluated through reviewing the Application for Research Involving Human Subjects and the accompanying documents. The Chairperson or Co-Chairperson have the authority to conduct this evaluation, or delegate it to two (2) members of the IRBPH. The Chairperson, Co-Chairperson, or two delegates will provide a written response to the Principal Investigator within one business day of the conclusion of the review. For a full review, the Chairperson or Co-Chairperson will distribute the full application package to all IRBPH members. Applications must be received a minimum of ten (10) business days in advance of the next posted IRBPH meeting to be assured of an opportunity to present that month. The Chairperson may waive the 10-day requirement. The Principal Investigator is required to attend a meeting of the full IRBPH and deliver a 10-15 minute presentation. The IRBPH reserves the right to request additional information or documentation prior to voting on a research proposal. The Chairperson will issue a written decision the following business day unless additional information is requested. The IRBPH may request further information, either in writing or by personal interview with the Principal Investigator. The IRBPH may also recommend improvements to the research plan, and defer final decision pending modifications. The IRBPH shall include in the approval notice the frequency with which it wishes to review and monitor the project once it is operational. The IRBPH shall conduct continuing reviews at intervals appropriate to the degree of risk, but not less than once a year (after date of initiation), and shall have the authority to observe the consent process and research. The Chairperson will exercise discretion, depending on the degree of risk of the research or other issues of concern, as to whether such review requires a review by the full IRBPH. For proposals involving children, review will be conducted at least every three months after initiation of the research. Proposed research may not be disapproved, nor may adverse action be taken regarding any project, unless the investigator(s) have been notified in writing of the cause for concern and have been given a reasonable opportunity to respond to the full IRBPH.

	The Principal Investigator is responsible for submitting a Request to Renew an Approved Protocol to the IRBPH a minimum of ten (10) days in advance of the last posted meeting before the deadline indicated in the initial approval, or most recent continuing review. Any substantive changes or modifications in the approved project must be submitted in writing to the Chairperson except where necessary to eliminate apparent and immediate hazards to the human subjects. Amendments or revisions to an approved project must be submitted in the same manner and numbered as the original proposal. The Principal Investigator is required to submit written responses addressing any questions the IRBPH has pertaining to the proposed changes. Two copies are required upon submission: a copy reflecting red-line track changes, and a clean copy. The IRBPH reserves the right to require an ad hoc continuing review to address any concerns resulting from a report of a substantive change to a research project. The IRBPH reserves the right to request verification from sources other than the investigator that no material changes have occurred since the previous IRBPH review. The IRBPH has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRBPH's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for IRBPH action and shall be reported promptly to the Principal Investigator, the Director, The United States Department of Health and Human Services (HHS) Office for Human Research Protections and the FDA where appropriate. In cases where the Chairperson judges that immediate harm may come to any subject or research, he/she may order a suspension of the project without advance IRBPH approval. In such cases the Director, the investigator, and all members of the IRBPH shall be notified of the Chairperson's actions and the reasons in writing within three (3) working days. If the investigator requests it, a meeting of the IRBPH shall be called within ten (10) working days to confirm, amend or revoke the action of the Chairperson.

	The IRBPH is responsible for reporting to the Director and Secretary of HHS or the Director of the FDA, any serious or continuing non-compliance by investigations with the requirements and determinations of the IRBPH. Upon completion of a research project approved by the IRBPH, the Principal Investigator must complete a closeout with the IRBPH. A proper closeout consists of: 1. Forwarding the final report of research activity to the Chairperson and the Director; 2. Submitting to the IRBPH documentation of all attempts to remove confusion, misinformation, stress, physical discomfort or other harmful consequences that may have arisen with respect to the participants as a result of the procedures; 3. Providing the staff of the relevant program(s) the purpose, nature, outcome, and possible practical and theoretical implications of the research in accessible language. In its regularly scheduled meetings, the IRBPH shall conduct business in the following order: 1. Review, discuss, and take necessary action regarding any reports of adverse events or harm coming to human subjects because of participation in any ongoing research. If a consent auditor has been appointed to oversee the consent process in any ongoing protocol, this person will be asked to report on his or her observations of the adequacy of the consent process being audited; 2. Complete all scheduled full reviews of proposed research at convened meetings at which a quorum of members are present. A quorum shall consist of a majority (more than half) of the current membership including the Chairperson; 3. Appoint a member or members, by majority vote, to undertake any desired continuing review(s). The appointed individual(s) shall be assigned to provide a written report to the IRB. Detailed minutes of every session of the IRBPH shall be maintained. The minutes will capture, at a minimum:

	1. Meeting attendance; 2. All actions taken; 3. The results of all votes: the number (but not the names of members) voting for, against, and abstaining; 4. A written summary of all of issues discussion, including the resolution. The IRBPH will maintain a file of approved research proposals for those with common research interests to exchange information, and coordinate activities. The file will also serve as a resource for research ideas and techniques of potential benefit. The IRBPH shall retain all meeting agendas, meeting minutes, applications, accompanying documentation, and correspondence for the period of time indicated in the DC Health Records Retention Schedule. The IRBPH shall issue an annual report prepared by the Chairperson every February first, to include: the number of projects; current members of the IRB; number of meetings convened; and significant policy issues addressed. Any employee out of compliance with any part of this SOP may be subject to commensurate disciplinary action.
V. Definitions & Acronyms	**Assent-** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. **Belmont Report-** A 1979 report published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. **Children-** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. For the purposes of most research, the age of consent is 18 years old. **Consent Auditor-** A person appointed by the IRBPH to ensure the adequacy of the consent process. This appointment will be made by the Chairperson when the IRBPH finds that a specific project

	involves a substantial question about the ability of a subject(s) to consent when there is a significant degree of risk involved. The consent auditor will be responsible only to the IRBPH and will not be involved with the research. The consent auditor will be familiar with the physical, psychological and social needs, as well as legal status, of the class of prospective subjects. **Confidentiality Agreement-** A document that recognizes the individual responsibility to hold specified data/information in confidence, and the potential legal penalties for unauthorized disclosure of confidential data/information. **FDA-** Food and Drug Administration **HHS-** United States Department of Health and Human Services **Human subject-** A living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. "Intervention" includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). "Identifiable private information" is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An "identifiable biospecimen" is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. **Informed Consent-** The process by which potential research participants learn about and understand the purpose, benefits, and

	potential risks of a research study, intervention, including clinical trials and what their participation will involve and then agrees to participate in the research study. The elements of Informed Consent are: 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental; 2. A description of any reasonably foreseeable risks or discomforts to the subject; 3. A description of any benefits to the subject or to others that may reasonably be expected from the research; 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; 6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; 7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; 9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator

for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

To satisfy the requirement for Informed Consent, the following additional elements shall also be provided to each subject as appropriate:

1. A statement of the general purpose of the study;
2. An explanation of why the subject was selected for the invitation to participate;
3. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
4. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
5. Any additional costs to the subject that may result from participation in the research;
6. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
7. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
8. The approximate number of subjects involved in the study; and
9. A description of any compensation the subject will receive for participation.

Informed Consent Form- A document embodying the elements of Informed Consent, signed by the subject or the subject's legally authorized representative, and retained in the patient's clinical record with a copy given to the signatory. The form may be read to the subject or the representative, but the investigator shall give

	either the subject or the representative adequate opportunity to read it before it is signed. **IRBPH-** Institutional Review Board for Public Health **Minimal risk-** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. **Principal Investigator-** a person who has primary overall responsibility for the development and submission of a research proposal for review. The principal investigator will have primary responsibility for the day-to-day conduct of a study and will be responsible for assuring that these activities are conducted in compliance with all current pertinent regulations and ethical and scientific standards. **Research-** A systematic investigation designed to develop or contribute to generalized knowledge. It includes any processes which seek ways to secure new information or organize pre-existing information in new ways, from or about human subjects or to introduce new untested procedures in the care, treatment, management or organization of human subjects which differ in any way from usual and customary medical, psychiatric, or other professional practice. **Somatic intervention-** An experiential intervention that brings attention to or consciously manipulates an individual's physical posture, gestures, gait, or breathing.
VI. Procedures	**Procedure A: Review Category Selection** 1. The applicant will complete the Review Category Selection Tool. 2. If the Review Category Selection Tool indicates the research project is exempt from IRBPH review, the applicant may complete the Application for Exemption.

3. The IRBPH Chairperson will review the Application for Exemption, and either grant or reject the exemption in writing.

4. If the exemption is rejected, the IRBPH Chairperson will direct the applicant to complete an Application for Research Involving Human Subjects.

5. The IRBPH Chairperson will determine if the research project must go through a Full Review (see Procedure B), or is eligible for Expedited Review (see Procedure C).

Procedure B: Full IRBPH Review

1. The IRBPH Chairperson will share the complete application package with all IRBPH members.

2. The IRBPH Chairperson, or designee, will inform the applicant of the review date.

3. The applicant(s) will present the research proposal.

4. The full IRBPH will deliberate in private, and vote on the proposal.

5. Members will indicate their approval or disapproval to conduct the research on a voting sheet, as well as recommendations.

6. Each member will return the signed and dated voting sheet to the Chairperson.

7. The Chairperson will tally the votes, indicating whether the IRBPH voted to approve, approve with conditions, or deny.

8. The IRBPH Chairperson will transmit a written decision the following business day. The written decision will clearly articulate the reasons for denial if applicable, and clearly articulate the restrictions if approved with restrictions. Any dissenting opinions offered by members are to be included.

Procedure C: Expedited IRBPH Review

1. The IRBPH Chairperson or Co-Chair will decide whether to conduct the review personally, or delegate to two IRBPH members.

2. The IRBPH Chairperson, Co-Chair, or delegates, will review the application package.

3. The IRBPH Chairperson, Co-Chair or delegates, will determine whether the proposal will be approved, approved with conditions, or denied.

4. The IRBPH Chairperson or Co-Chair will transmit a written decision to the Principal Investigator the following business day, copying all IRBPH members and the Director. If the application is denied, the written decision will clearly articulate the reasons for denial and requirements with which s/he must comply to secure approval, and clearly articulate the restrictions if approved with restrictions.

Procedure D: Continuing Review of an Approved Protocol

1. The Principal Investigator will complete the Request to Renew an Approved Protocol.

2. The Principal Investigator will submit the Request to Renew an Approved Protocol a minimum of ten (10) days in advance of the last posted meeting date before the deadline indicated in the initial approval, or most recent continuing review.

3. The Chairperson, or Co-Chairperson, will review the Request to Review an Approved Protocol and respond to the Principal Investigator within three (3) days indicating:
   a. Whether the renewal will be approved based upon documentation alone, or will require a meeting of the full IRBPH;
   b. Whether verification from sources other than the investigator that no material changes have occurred since the previous IRBPH review will be required.

	4. If required, the full IRBPH will convene to review the request for renewal. 5. See Procedure A; Steps 4-8.
VII. Contacts	IRB Chairperson IRB Co-Chairperson
VIII. Related Documents, Forms and Tools	Review Category Selection Tool Application for Research Involving Human Subjects Application for Exemption Request to Renew an Approved Protocol